



New Medicines. New Hope.



**Communicating Benefit and Risk:  
A View from the Pharmaceutical Industry  
International Symposium on Understanding  
Health Benefits and Risks**

Alan Goldhammer, PhD; Vice President for Scientific and Regulatory  
Affairs

# **WHAT THE PUBLIC WANTS (and maybe expects)**



- **All Drugs work All the Time for All People**
- **All Drugs are Safe All the Time for All People**
- **All Drugs are Cheap All the Time for All People**

**The Reality is that none of the above three are true.**

# IS THE UNIVERSAL BLACK BOX WARNING THE SOLUTION???



This drug poses both known and unknown risks. Some of these risks may be severe and even result in death. The known risks are described in this product label. The unknown risks are still unknown.

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# Key Facts



## Research and Development

- **Time to develop a drug = 10 – 15 years<sup>1</sup>**

## Development Costs

- **Cost to develop a drug**  
**2006 = \$1,318 million<sup>2</sup>**  
**2001 = \$802 million<sup>3</sup>**  
**1987 = \$318 million<sup>3</sup>**  
**1975 = \$138 million<sup>3</sup>**
- **Cost to develop a biologic**  
**2006 = \$1.2 billion<sup>4</sup>**

## Percentage of Sales That Went to R&D in 2007

**Domestic R&D as a percentage of  
domestic sales = 18.7%<sup>5</sup>**

**Total R&D as a percentage of  
total sales = 16.4%<sup>5</sup>**

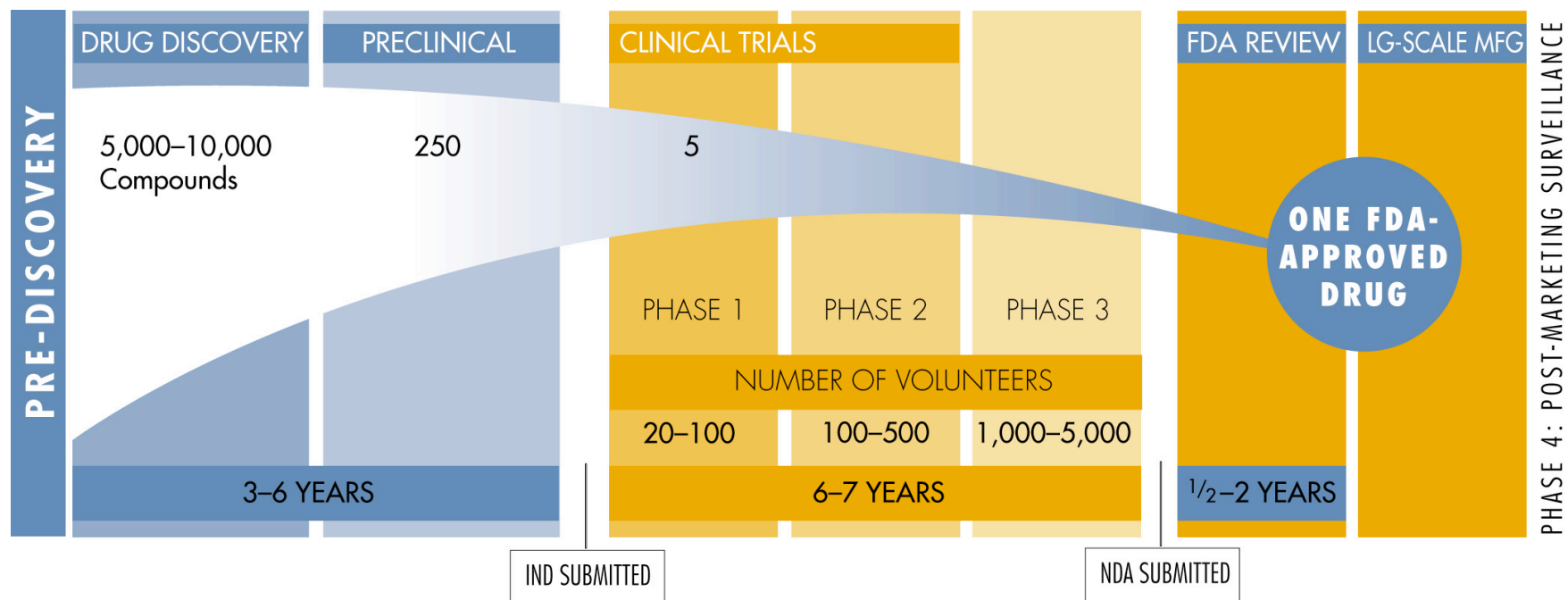
## R&D Spending

Year	PhRMA members <sup>6</sup>	Total industry
<b>2007</b>	<b>\$44.5 billion (est.)</b>	<b>\$58.8 billion (est.)<sup>7</sup></b>
<b>2006</b>	<b>\$43.4 billion</b>	<b>\$56.1 billion<sup>8</sup></b>
<b>2005</b>	<b>\$39.9 billion</b>	<b>\$51.8 billion<sup>9</sup></b>
<b>2004</b>	<b>\$37.0 billion</b>	<b>\$47.6 billion<sup>10</sup></b>
<b>2000</b>	<b>\$26.0 billion</b>	<b>not available</b>
<b>1990</b>	<b>\$8.4 billion</b>	<b>not available</b>
<b>1980</b>	<b>\$2.0 billion</b>	<b>not available</b>

- **2008 = \$28.9 billion**
- **2007 = \$28.6 billion**
- **2006 = \$28.5 billion**

Sources: See Key Facts Sources slide.

# Figure 2 The R&D Process: Long, Complex, and Costly



# Drug Development in an Interactive Process



- **FDA is Consulted from the Early Stages of Development Regarding Clinical Trial Protocols**
- **FDA Receives and Reviews all the Data**
- **FDA Ultimately Approves the Drug Label from which all Communication about the Drug Flows**

# TWO CRITICAL ISSUES IN DRUG DEVELOPMENT



- **Cost – Current Estimate to Bring a New Molecule to Market is Approximately \$1.3 Billion**
- **Time – Because of Scientific Uncertainties and Regulatory Compliance it takes 10-15 years from Discovery to Licensure**

**Despite this effort, we don't fully know the drug's safety profile (or for that matter the full efficacy)**

# HOW DO WE MEASURE SUCCESS?



**Drug Approval =  $f(\text{benefit/risk})$**

- **Benefit – Expected Positive Clinical Outcome**
- **Risk =  $p(\text{harm}) \times \text{severity}(\text{harm})$**
- **The overall assessment of risk is dependent on the benefit (and the severity of the medical indication being treated)**

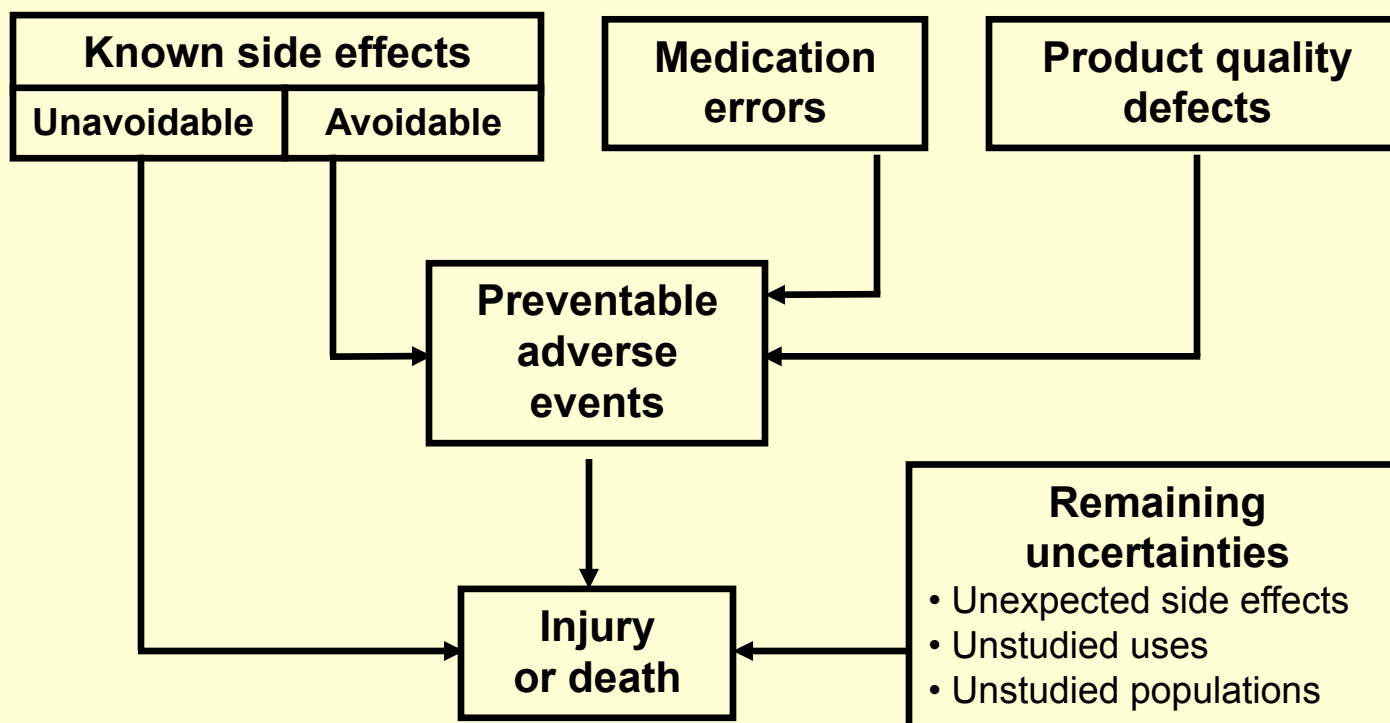


# THE ROADMAP TO SUCCESS



- 1) Identify the Therapeutic Target (enzyme/receptor)**
- 2) Translate *in vitro* Observation to *in vivo* Activity**
- 3) Identify Safety Issues (pre-clinical & clinical)**
- 4) Demonstrate Efficacy**
  - Keys to Steps 1-4 is Deciding when to Pull the Plug (e.g., stop development)
- 5) Continue to Study Safety (post-market)**

## Sources of Risk from Drug Products



# HOW TO COMMUNICATE BENEFIT & RISK



- **Drug Label (Package Insert)**
- **Patient Package Insert**
- **Medication Guide**
- **Consumer Medical Information**
- **DTC**
  - Print, Broadcast, Internet
- **Other Sources (FDA; Internet)**

## **TWO SMALL (or VERY BIG) STEPS**



**Let's all work to insure that every patient has realistic expectations about the medicine they are prescribed.**

**Make sure that the patient has the right drug at the right time for his/her medical condition**